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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
National Center for Environmental Assessment
Washington, DC 20460

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MEMORANDUM

DATE: **March 7, 2003**

SUBJECT: **Review of "A Quantitative Health Risk Assessment for the Kalamazoo River PCB site" prepared for the Kalamazoo River Study Group by Cambridge Environmental Inc.**

TO: **William Muno, Director**
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Introduction

The report entitled "A Quantitative Health Risk Assessment for the Kalamazoo River PCB site" dated June 1, 2001, along with its September 2002 update, (KRSG Report) documents a probabilistic risk assessment for people exposed to polychlorinated biphenyl (PCB) contamination in and around the Kalamazoo River. We understand that these documents were submitted to US EPA Region V as final documents, without the prior input from EPA and other relevant parties that is recommended under Superfund Guidance for probabilistic risk assessment (EPA 2001). The conclusion of the assessment is that further action to PCBs from the river may not be needed. This conclusion is based on a calculated "plausible, high-end, estimate of individual cancer risk [of] 1.7 in 100,000" and a "plausible high-end hazard index [of] ... 0.81." The September 2002 update reports that "Using a fixed [rather than probabilistic] toxicity [cancer potency] value, cancer risks are less than 10^{-4} for better than 90% of random individual

Kalamazoo fish consumers" In addition, this update reports that "no non-cancer risks are expected because the 90th percentile of randomly-chosen individuals were exposed to a dose lower than the HPV [Great Lakes States Health Protection Value for PCBs]."

This review has examined exposure assumptions and modeling for the fish consumption pathway, which appear to be the "drivers" for the risk assessment for the Kalamazoo site. Due to a need to focus our efforts, we did not review the distributional analysis suggested for health effects data on PCBs or exposures from the soil/sediment contact pathways. We note that EPA Probabilistic Risk Assessment guidance has not recommended the application of Monte Carlo methods in evaluation of dose response assessments.[1]

The assessment does contain a commendably complete attempt to develop a population model of PCB exposure from consumption of fish from the Kalamazoo River by fishers and their family members. The assessment takes an appropriate approach, consistent with EPA guidance, in that it develops separate distributions reflecting population variability and uncertainty. This so called "double loop" approach allows estimates of percentiles of population exposure as well as uncertainty bounds on those values. Where data are adequate, this approach can provide much information to risk managers. It is also valuable that the assessment took into account some correlations between variables, most notably, duration of fish eating and amount of fish consumed. Correlations between variables have too frequently been overlooked in Monte Carlo analyses.

However, we do have concerns about the extent to which the assumptions and models presented in the assessment go beyond what the available data can reliably support. In particular, some of the assumptions underlying the analysis as well as the report's interpretation of the results likely lead to a systematic underestimate and understatement of the impacts of PCB contamination on reasonably maximally exposed individuals. We also have concerns about whether the specific results presented are sufficient to provide the most pertinent information for risk management decisions for this site. These issues will be discussed below.

One limitation of the assessment document was the lack of a concise and specific presentation of steps taken in the Monte Carlo calculations. For example, the document does not present graphical or tabulated distributions for some of the important variables in the assessment (e.g., the utilized distribution for fish eating duration, where inputs, but not the final distribution are given.) While further documentation was provided in the form of QuattroPro spreadsheets, this is not a transparent approach, even to reviewers experienced with Monte Carlo methods.

General issues

Subpopulation of Subsistence Angelers

The KRSG report bases its exposed population on the group surveyed in the Kalamazoo River Angler Survey. The population surveyed included anglers of all sorts who were interviewed in the field in Kalamazoo and Allegan counties. The KRSG report considers as its "reasonably maximally exposed population" those individual who eat fish they caught with behavioral characteristics defined by the survey.

The Risk Assessment Guidelines for Superfund states that, when considering an exposed population one should:

> [r]eview information on the site area to determine if any subpopulations may be at increased risk from chemical exposures due to increased sensitivity, behavior patterns that may result in high exposure, and/or current or past exposures from other sources. (EPA 1989)

In particular, several studies have indicated that *subsistence* anglers -- individual who would not be able to meet their daily nutritional requirements without sport-caught fish -- are a significant subpopulation that may be at increased risk. In particular, three groups of subsistence anglers has been identified and evaluated in several studies in the Great Lakes region: low-income/minorities, Native Americans, and Hmong. For instance, at other Superfund sites, the Hmong population has made up a significant fraction of the subsistence fishing population (MDH 2002).

However, subsistence anglers were not specifically targeted in the survey used in the KRSG report to define the exposed population. For instance, survey interviewers reported that they were unable to interview Hmong anglers that have been observed fishing in the Lake Allegan area. Therefore, it is likely that the exposed population analyzed in the KRSG report is a mix of subsistence and occasional fish-eaters. In fact, only about 4% of the Allegan County anglers and none of the Kalamazoo County anglers reported that they fished for food only. Moreover, about half of the respondents who reported eating fish reported that they had been doing so for only five or fewer years. In addition, of those who reporting eating fish and who indicated a meal frequency, over half reported eating fish less than once a month. These statistics are not consistent with a subsistence population. By contrast, the Human Health Risk Assessment by the Michigan Department of Health (MDH 2002) did consider a subsistence population as a separate subgroup. The MDH assumed that this subgroup had an exposure period of 30 years and ate fish approximately every other day. The net difference in total lifetime fish intake between the MDH subsistence population and the mean of the KSRG distribution is about a factor of 20.

EPA's policy guidance is for risk assessments to consider distinct sub-populations that may be at increased risk. The KRSG report's delineation of the reasonably maximally exposed population does not separately consider the distinct sub-population of subsistence anglers, and thus systematically underestimates the exposure and risk to such populations. In particular, a subsistence population is likely to eat fish more often and for a longer period than the population sample used by the KSRG report.

Cumulative exposures to current fish consumers

All exposures are calculated from 1999 onwards. While it is not always standard EPA procedure, to provide full information for decision makers and the public, an assessment should provide information on estimated lifetime exposures for the current fishing population - noting that, per survey results, exposures began in previous years for most individuals. The issue of total lifetime exposures is relevant for both cancer and non-cancer risk assessment. The judgement about whether lifetime risks will exceed a reference value (or equivalently whether the hazard index will be elevated) depends on an individuals cumulative exposures – including both past and future exposures. To the extent that risk management decisions focus on future exposures, an analysis could have been performed to show the extent which total lifetime exposures are attributable to future exposures. For non-cancer risks, this would have involved comparison of the differences between a distribution for past exposures and the total exposure distribution. Information on individuals' cumulative exposures is also important for cancer risk assessment from an informational perspective. The issue of presenting risks to the current fishing population will also be discussed below regarding the distribution for exposure duration.

Also relevant are exposures to PCBs that Kalamazoo fish eaters may receive from self caught fish from other water bodies. The survey data used in the assessment addresses how much fish the fishers and their families consume from the Kalamazoo River specifically. However, active fishermen will often fish in more than one water body, and therefore would have an additional " background" exposure to which the Kalamazoo specific exposures add onto.

Children's exposures

It is stated that for the population addressed, most of the exposure for the more highly exposed individuals occurs during adulthood, where "age-dependent factors are fairly constant". This conclusion may be biased by a simplification in the application of the survey data. The exposures for interviewed fishers appear to have been extrapolated by a multiplicative factor to also include other fish eaters (i.e., family members). The ages at which fish eating occurred appears to be based on the survey (mostly adult) fishers and not for children in their families. While data on the specific ages at which children's exposures started were not collected, many children were reported to eat fish from the Kalamazoo. On average, Kalamazoo river anglers had 1.3 children ages 5-18, and 0.3 children under 5 who ate fish (from Table 8 of the survey report). By comparison, the mean numbers of children per fish eating household who did not eat Kalamazoo fish were 0.4 for 5-18 year olds and 0.3 for children under 5. Thus, in these households, it appears that about 75% of the children ages 5-18 and 50% of the children under 5 consumed fish from the Kalamazoo River. Therefore the assessment would have been substantially strengthened if it included a specific consideration of risks to children eating fish from this site. Because of the concern about children as a distinct subpopulation, it would have been appropriate to have addressed their exposures in a subsidiary analysis (which, given available data for the site, will involve additional assumptions), rather than as part of the overall population analysis.

Distributions shown for a "random individual" are difficult to interpret

The document suggests that for a randomly selected individual there is "no difference between variability and uncertainty" (as discussed on page 6-30). This construct may be arguable in a certain mathematical sense, however it does not fit with the needs for decision makers who wish to understand population variability as well as the uncertainty in such estimates. This issue was addressed in EPA's Monte Carlo guidance, where it is recommended that assessments not mix uncertainty and variability into a single distribution. For purposes of comparing Monte Carlo estimates with "high end" or "RME" estimates from non-probabilistic an appropriate approach would be to compare the point estimates with high end risk percentile values from the PRA, e.g., the 90^{th}, 95^{th} and 99^{th} - and the uncertainty bounds for these percentiles. For this reason, the presentation in Chapter 8, comparing Michigan's HHRA results with the PRA output was difficult to interpret. That discussion was framed in the context of the "random individual" construct; the assessment provided enough information to allow a more useful comparison with estimated percentiles (and their bounds) from the variability distribution.

Local versus more distant residence

It was interesting to note in Table 6.10 how many survey respondents reported only 1 or a few years of fish eating from the Kalamazoo River. It would have been important to compare this result with other surveys of fishers to gain an understanding of how ordinary this pattern of behavior is. One issue for interpretation is that the MiCPHA states that a proportion of interviewed fishermen particularly in Allergan Co were not local but visited from other counties or states. These fishermen may be less likely to have an continuing duration of consumption of Kalamazoo fish as compared with local individuals, or to eat this fish as regularly. It would have been useful to see if the distribution of durations changes if the results were analyzed for local residents.

<u>Concentrations in fish</u>

Use of mean concentrations

We agree that it is appropriate to focus on estimating mean PCB concentrations in fish consumed by fishers and other eaters. It is not generally necessary to model intake concentrations based on individual fish unless a person eats few total fish (and would be at much lower risk as compared with regular consumers) or in the instance where a few fish might have inordinately high concentrations compared to the population of fish – a situation that does not seem to pertain to this assessment. As those who eat fish with some regular frequency will eat a substantial number of fish meals in a period of relevance to a chronic assessment, their exposure can be appropriately estimated by a mean value. As the distributions of PCB concentrations in fish can be expected to have substantial skew (long right tails) estimation and uncertainty analysis need to take this property into account. The assessment addresses this by using the uncertainty estimates based on a mean of a lognormal distribution. This approach appears reasonable in theory, but we did not review its specific implementation.

Uncertainty in time trends

The time trend estimated in the assessment is being projected to apply many years into the future. The model of fish concentration over time as applied in the current assessment is based on fish PCB measurement data collected for 1993 to 1999, while the risk calculations in the assessment apply to fish concentration estimates for 1999 and later years. As an extrapolation, rather than a descriptive interpolation of the data, the potential for uncertainty needs careful attention. In order for an assessment to rely on such a projection, it is critical that time trend data be robust and reliable. While the authors of the assessment report a statistically significant coefficient for time trend in their data analyses, an inspection of the data presented do not suggest that a robust or reliable time trend can be projected. It would have been valuable to have had a more complete presentation of the model, including graphics of fit and standard regression model diagnostics.

Assessment Tables 6.3 and 6.4 present concentration measurement data for carp and smallmouth bass by sampling area and year. The tables below summarize the data on mean concentrations.

Mean concentration data for carp (source: table 6.3), generally based on 11 fish samples per cell

Sampling Area

Year	1	2	3	4	5	6	7	8	9	10
93	0.16	0.72	5.0	7.4	6.3	3.8	3.0	5.1	1.9	8.2
97	0.18	0.39	--	--	6.3	--	--	--	0.86	--
99	--	0.62	--	6.9	10.4	--	--	3.0	1.9	--

Mean concentration data for smallmouth bass (source: table 6.4), generally based on 11 fish samples per cell

Sampling Area

Year	1	2	3	4	5	6	7	8	9	10
93	0.21	0.37	1.2	0.54	2.0	1.1	1.6	2.2	3.7	--
97	0.15	0.20	--	--	0.56	--	--	--	0.61	--
99	--	0.34	--	0.78	0.58	1.2	--	0.83	0.65	--

Inspecting the carp data there is a lack of any convincing overall time trend. Note that only two of the four sampling areas for which comparisons could be made showed lower concentrations in 1997 as compared with 1993, and that in both of these the 1999 value was again close to or equal to the the 1993 value. For the three areas which had sampling data in all three years none showed a continued pattern of decrease.

Looking at the bass data, the four areas with sampling data in 1993 and 1997 show an indication of a decline, however in three the three areas where 1999 data were also available, the concentrations are steady at the 1997 values or show some upward movement. Among the three locations with only 1993 data and 1999 data, two show a modest increase, while one has a decrease.

This comparison is not meant to suggest that statistical results showing some trend in the data are invalid, but rather it indicates that any trend that is present here is tenuous – and would be risky to project into the future.

Moreover, over a long time period, the assumption of first-order (exponential) decay would have a major effect on the assessment results, and thus there is a significant concern about this assumption. For instance, floods and ice scouring can lead to significant departures from first-order decay by disturbing sediment layers.

To summarize, the projection of a continuing exponential reduction of PCB concentrations in fish is conjectural. The actual data on concentrations in fish in the period used in the analysis (1993 - 1999) do not appear to provide a robust indication of a continuing decline.

Geographic differences in risk

It is reasonable that the assessment assumes a geographic regularity in a person's fishing behavior, with mean fish concentrations estimated by specific river sampling areas (ABSAs). It can not be expected that an individual would fish randomly over a substantial length of river. However, it would have been valuable to have had model outputs stratified by river sampling area. Concentration estimates for fish in different river sampling areas varies substantially, thus risk will vary by location fished and this information should be made available to decision makers.

Catfish

A significant uncertainty in the data base may pertain to consumption of catfish. Catfish appear to be the most frequently consumed species. Table 6 of the survey report indicates that catfish were consumed by 84% of respondents who ate fish (see also Figure 6.6 of this assessment). Catfish, as an oily, bottom dwelling species, have often been found to have relatively high concentrations of PCBs. However, it appears that data on catfish concentrations as used in this assessment are very sparse—Table 9 reports data only for one location and only in 1999. This data point happens to be at a location where the mean concentrations of the similar fish carp (also an oily, bottom dwelling species) are a factor of more than two lower than for the average among the locations, and a factor of more than four lower than for the location with the highest concentration. If catfish and carp have substantially correlated PCB concentrations, which is plausible given the similarities between the species, then the use of the single catfish data point would lead to an underestimate in human PCB intakes. Thus, the lack of data on catfish substantially increased the overall uncertainty of the assessment.

<u>Duration for fish eating</u>

Individuals will drop in and out of fishing activity, but it is widely recognized as a strong avocation for many who will pursue the sport for many years. The analysis in the Kalamazoo assessment, taken at face value are instead suggestive of a rather transient population. There is more than one issue involved in this matter.

Steady state assumption is uncertain

First, the assessment's methodology for estimating a distribution of residence duration applies data from the survey, but transforms it using a methodology developed for residence duration published by Israeli and Nelson (1992). This approach makes heavy reliance on a steady state assumption: namely that population characteristics and distributions of behavior do not change over time. The Kalamazoo assessment acknowledges the reliance on this assumption. However, the assessment does not provide data or a convincing rationale for acceptance of the assumption. There are several reasons for concern that the steady state may not be inappropriate.

The assessment acknowledges that in the past that the Kalamazoo River was less suitable for fishing. It is not clear from the assessment just what the time course for improvement in the river may have been, or when it developed an active fishing population. The high end of population risk would be among individuals who make the longest use of the resource. Therefore, if the river were less usable in the past, then the survey data would have been truncated for long durations of fishing. The extrapolation of the survey data on past use to future use patterns would then incorrectly imply that long durations of exposure are highly improbable, and therefore potentially underestimate the future population of long-term fishers.

A fishing advisory issued by MDPH in 1977 recommend against any consumption of fish from the Kalamazoo river. This was in place until 1983, when the advisory was modified to provide some suggested allowable intake rates (only for some species, and not for children or females who are or may become pregnant). This raises two issues: first that the fish consumption practices may have changed over time as fishers received different advice on whether any consumption of Kalamazoo River fish was acceptable. Secondly, consumption patterns may change in the future if advisories are lifted or if concerns about the river are perceived to diminish. Depending on location, 60 to 72% of fishers in the MiCPHA survey expressed concerns about safety of fish.
It is therefore plausible that current conditions, with the fish advisories in place, lead to an underestimate of the amount of fish consumption which would occur if those advisories were lifted. Such an underestimation would probably be a combination of reporting bias and actual behavioral changes which would occur. Therefore, the use of recent survey data on the Kalamazoo River likely underestimates the actual behavioral patterns which would occur if no additional cleanup were to occur and fish advisories were lifted.

Due to these concerns, the distributional assumptions for duration are quite open to question, and the likelihood for occurrence of longer consumption durations in the future should be anticipated. Again, note that the assessment as presented applies only to consumption patterns in future years.

Duration distribution not applicable to current fish eating population

Secondly, while it may not be transparent to the reader, the duration distribution derived in the assessment for individuals "who start eating fish in 1999" would be substantially different from a distribution appropriate to current users of the resource. It is projected that many individuals will consume fish for short periods of time (i.e., one year). While there is not any objection to trying to track such individuals, such an analysis is not indicative of the durations for actively engaged fishers. The active population of fishers will tend to include people with less transient behavior. It would have been important to include distributions for duration for people starting on a given date should have been re-weighted to provide an estimate of duration for the current fishing population. (Technically this could have been accomplished by re-sampling from the duration distribution with a probability proportional to duration). Inclusion of such calculations would have substantially strengthened the utility of the assessment for interpreting risks for the local fishing community.

To summarize, the duration estimates for fish consumption for anglers and their families should have been qualified. The estimated distribution relies on an assumption that there have been and will not be significant changes in the fishing eating behavior in the population. There are indications that this is not the case, and durations in the future may be longer. Additionally, the distribution that is used is not applicable to the current fish eating population. Due to the statistical properties of the modeling, the distribution for the current fish eating population would be expected to would be shifted towards longer durations as compared with the distributions provided in the assessment (for individuals who begin fishing in 1999).

Effect of additional exposure period (considering biological half-life for PCBs)

The goal of the correction – to account for the "area under the curve" of internal PCB exposure – seems appropriate, although we did not review details of these calculations. Region V should note, however, that this approach is not part of EPA's risk assessment guidance, nor does it appear to have been peer-reviewed. The overall effects appear to have been a relatively modest, though not insignificant effect on the bottom line. We would note that terming this factor the " additional exposure period" seems somewhat misleading, as it sometimes takes on negative values (i.e., adjustments to decrease duration of exposure period are made for adult groups – whereas effective durations are generally increased for children). However, as noted above, it appears that the age of first exposure is obtained for currently active adults (presumably most of the interviewed fisher population). Age at first exposure for children eating fish caught by parents does not seem to have been obtained in the surveys. This latter circumstance suggests that accuracy of the attempted "additional duration" corrections is open to question. It would have been useful if the assessment had addressed this latter issue and provided results with and without the duration adjustment.

Meals eaten per year

Some further consideration of the responses from the fish eating questions from the MiCPHA angler study would have been useful. First two different questions addressed fish eating, one asked the fisher how often "the fish you catch" in the Kalamazoo River are eaten in your household. The second question asks what species of fish from the Kalamazoo are eaten in the fishers household and an approximate number of meals per year per species. While the later question did not ask about consumption frequency for all fish apparently this was written in on some forms. The Monte Carlo analysis relied on the second question, adding up frequency estimates for different fish species. It would have been valuable to compare the consistency of the the two questions. Respondents may find it more difficult to estimate numbers of fish meals eaten per year by species as compared with providing a total.

One important result of the analysis is the finding of a rather strong relationship between fish eating duration (duration to date for surveyed fishers) and number of meals eaten per year (Figure 6.5). This figure suggests that fishers with the longer duration of eating (4^{th} quartile group) had central values for eating frequency approximately 4 times as high fishers who reported a short duration of consumption (1^{st} quartile group) – a median of approximately 20 fish meals versus 5 fish meals per year. This analysis provided valuable information. Relatively few environmental Monte Carlo assessments have addressed this type of issue as yet.

Meal size

Given the correlation seen with eating frequency and eating duration, it would have been valuable to see if meal size correlated with these two measures (that are indicative of the fishers commitment to fishing and presumably their fishing skills).

There appears to be some difference between the available survey in handling of meal size data. Respondents in the Atkin (1994) survey were asked about mean size in terms three broad ranges of small, medium and large, with "large" described as "greater that 10 oz." In the assessment, the "large" meal category (which about one third of respondents reported as their usual meal size) was treated as 12 ounces. On the other hand MiCPHA (Phase 2) study discussed as being consistent with the MiCPHA results in the text above had categories up to > 16 ounces. Thus the effective truncation of the meal size data may have reduced overall variability to a degree.

Effect of cooking

The analysis of the effect of cooking on reduction of PCB levels in consumed fish seems reasonable and is based on substantial data from a variety of published studies using different cooking methods. The distributions applied in the assessment do rely substantially on judgement to apply experimental data to the human exposure situation.

Estimation of population effected

The assessment attempts to derive an estimate of the total population of fishers using the Kalamazoo river from existing survey data. The MiCPHA study does not appear to have been designed to support this purpose, and while the assessment makes a creative attempt to apply the data, it is not clear how large the uncertainties in the projections may be. The result may more reasonably considered as a range finding exercise rather than an estimate based on statistical sampling. One issue, recognized by the assessors, is there does not seem to be a reliable way to estimate the probability that the survey would locate and interview a fisher who was active on a survey day. The authors approached this by assigning a judgement based uncertainty distribution to this probability, however we don't have a way to ascertain the validity of the inputs – e.g., the central assumption that "targeting of popular spots compensates for the missing of anglers who arrived after or left before" the survey personnel visited a specific location. It would seem that targeting popular spots could work either for or against full identification of the fishing population. Since no fishermen are interviewed more than once, repeat visits to popular spots may not turn up more fishers as compared less frequented locations that may not be intensively surveyed. Given the limitations we cannot recommend that the suggested uncertainty distribution of population size for use as a quantitative input for the assessment. It would be important to check whether there is not some other data for this population – perhaps regarding participation in fishing activities – that would provide a perspective on population size. (We also note that formula 6.23 and other assumptions used in the estimation of population size were difficult to follow. The derivation of this formula is not specifically explained, and it was not clear how the duration of the survey period (n=151 days) could be used instead of 365 days in a year, as the variable from the MiCPHA survey refers to numbers of times fished per year.)

Presentation of Numerical Results

The KRSG report tends to report their input parameters and results in terms of medians and numerical percentile values. While this is useful, it should be noted that because many of the parameters and variables in the calculation are treated as lognormally distributed, the tails of these distributions can be quite long. In particular, the difference between the median and mean as a measure of central tendency can often be a factor of several-fold, even greater than a factor of 10 if several parameters are multiplied together.
For instance, in the distributions used for the number of fish meals per year and the length of time eating fish, the means are each a factor of two or more than the medians. Because these quantities are multiplied together in the exposure assessment, the result is that the total lifetime fish consumption has a distribution in which the mean is a factor of more than four greater than the median. Therefore, as a matter of interpretation, the KRSG report's use of medians and certain percentiles, especially when comparing with the values used in other assessments, de-emphasized the sometimes significantly higher average or expected values of human health impacts.

Observations Regarding KSRG Variability and Uncertainty Distributions

Although there are a number of factors which likely lead to underestimation of risk and therefore call into question the suitability of the KSRG approach in risk management decision-making, we note some interesting observations. EPA guidance and Superfund risk assessment goals place emphasis on high end percentiles of the exposure distributions and the uncertainties in these percentile estimates. Cancer risk estimates of this form are shown for lifetime average daily dose in Figure U.5 of the Sept. 2002 update; for non-cancer assessment, results of this form on the average daily dose during the exposure period are shown in Figure U.8. Differing from the suggestions in the assessment, we suggest that the "random individual" approach, as incorporated in Figures U.9 - U.12 in the update, do not fit with EPA guidance on Probabilistic Risk Assessment, as they do not allow decision makers to understand the differences in uncertainty and variability as they are relevant to consideration of environmental risks.

Even with likely underestimations in risk, inspecting Figure U.5, it can be seen that for the 95th percentile exposed individual the majority of the uncertainty distribution falls above the 0.5 μ g/kg-d dose associated with a 10^{-4} cancer risk level (using EPA's cancer potency estimate of 2 $(mg/kg\text{-}d)^{-1}$). Upper bounds on the exposure of the 95th percentile individual are on the order of $3x10^{-4}$ risk. Most of the uncertainty distribution for the 99th percentile individual exceeds a cancer risk level of 3×10^{-4}, with upper bounds for this percentile of exposure being at a risk level of approximately 10^{-3}. While the "MLE" values are shown on these curves as central estimates of the risk at a particular percentile, the term "maximum likelihood estimate" refers to a particular statistical technique and should not be taken to imply that there should be a preference for these values in risk assessment. Note that the median values (at 0.5 cumulative probability) from the curves exceed the MLEs. The expected values of risk for upper percentile individuals, while not provided for these curves, will be above, and maybe substantially above, the medians.

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[1] As noted above, we did not review the methodology used to generate a distribution for cancer potency of PCBs. EPA currently recommends an upper reference value of 2 $(\text{mg/kg-d})^{-1}$ for the cancer potency for food chain and soil exposures as these pathways involve environmental processes (retention of more persistent and toxic cogeners) which are likely to increase risk from PCBs (EPA 1996). However, it is worth repeating two observations presented in the assessment. First the cancer potency distribution derived in the assessment would place the EPA cancer potency of 2 $(\text{mg/kg-d})^{-1}$ at the 77th percentile of the calculated uncertainty distribution for this variable – i.e., not in the far tail or even at the 95% confidence limit. Secondly, the "expected value" – that is the overall average of the suggested distribution for the cancer potency term – would actually be 4.4 $(\text{mg/kg-d})^{-1}$, somewhat in excess of the EPA value.